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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,229	04/11/2001	Avram Scheiner	279.337US1	2999

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EXAMINER

DROESCH, KRISTEN L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,229

Applicant(s)

SCHEINER ET AL.

Examiner

Kristen L Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 56-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 56-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 16-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The non-statutory subject matter is the human body (i.e. the left side of the heart and the right side of the heart). To overcome the rejection, the examiner suggests using functional language such as "adapted to be disposed in the left side of the heart".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 1-3, 8-11, 13-16, 19, and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlson et al. (5,792,195). Carlson et al. shows a first heart sound sensor, (34) a second cardiac electrical signal sensor (24), a third cardiac electrical signal sensor (26), an interface circuit (42) and a control circuit (32) (Fig. 2).

Regarding claims 2-3, 10-11, and 21, Carlson et al. further shows the heart sound sensor is an accelerometer (34) located internal to the implantable housing (10)

With respect to claims 8, 19, Carlson et al. shows the data transmitted is processed data (Col. 4, lines 46-62).

Regarding claim 13, the second sensor includes an EGM sensing electrode (16,18,20,22) and the second signals are representative of EGM electrical signals.

Regarding claims 14-16, and 22, Carlson et al. shows the second sensor (24) includes an atrial sensing electrode (20, 22), and the third sensor (26) includes a ventricular sense electrode (16,18) wherein the second sensor is disposed in the right side of the heart

5. Claims 1-3, 8-11, 13-16, 19-22, 56-59, and 62-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Daum (6,453,201).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With respect to claims 1, 9, and 20, Daum et al. shows a first heart sound sensor, (50) a second cardiac electrical signal sensor (24), a third cardiac electrical signal sensor (34), an interface circuit (40) and a control circuit (10) (Fig. 1).

Regarding claims 2-3, 10-11, and 21, Daum et al. further shows the heart sound sensor is an accelerometer (50) located internal to the implantable housing (10) (Col. 3, lines 4-8).

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With respect to claims 8, and 19, Daum et al. shows the data transmitted is processed data (53).

Regarding claim 13, Daum et al. shows the second sensor includes an EGM sensing electrode (24, 34) and the second signals are representative of EGM electrical signals. (Col. 2, lines 4-7, 54-66).

With respect to claims 14-16, and 22, Daum et al. shows the second sensor (34) includes an atrial sensing electrode, and the third sensor (24) includes a ventricular sense electrode, wherein the second sensor is disposed in the right side of the heart

Regarding claims 56-58, Daum et al. shows a method of outputting heart sounds using an implanted sensor comprising detecting heart sounds using a first implanted sensor, transmitting data representative of heart sounds to an external system, detecting first and second cardiac electrical signals using a second and third implanted sensor and transmitting data representative of the first and second cardiac electrical signals to the external system (Col. 3, lines 35-46).

With respect to 59, Daum et al. shows generating control signals using first data representative of heart sounds from the implanted system; applying control signals (trigger) to an output device (12) to generate outputs that are representative of the detected heart sounds. (Col. 2, lines 15-21, Col. 4, lines 1-8)

Regarding claim 62, Daum et al. shows generating control signals (trigger) from second data representative of first cardiac electrical signals from the implanted system; applying control signals (trigger) to an output device (12) to generate outputs that are representative of the detected heart sounds. (Col. 3, lines 37-39, Col. 2, lines 15-21, Col. 4, lines 1-8)

With respect to claim 63, Daum et al. shows outputting relative timing information between the heart sounds and the first cardiac signals on the output device (12) (Col. 3, lines 38-40).

Regarding claim 64, Daum et al. shows generating control signals (trigger) from third data representative of second cardiac electrical signals from the implanted system; applying control signals (trigger) to an output device (12) to generate outputs that are representative of the detected heart sounds. (Col. 3, lines 37-39, Col. 2, lines 15-21, Col. 4, lines 1-8)

With respect to claim 65, Daum et al. shows outputting relative timing information between the heart sounds and the second cardiac signals on the output device (12) (Col. 3, lines 38-40).

6. Claims 56-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Turcott (6,409,675). With respect to claim 59, Turcott shows a method of outputting heart sounds using an implanted system including receiving first data representative of detected heart sounds (Col. 7, lines 37-40), applying control signals to an output device to cause the output device to generate outputs representative of the detected heart sounds (Col. 13, lines 60-65).

With respect to claims 57-58, Turcott shows detecting first and second cardiac electrical signals using a second and third implanted sensor and transmitting data representative of the first and second cardiac electrical signals to the external system (Col. 15, lines 35-49).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Lekholm (4,763,646). Although Carlson et al. discloses the claimed invention except for the heart sound sensor being located externally from the implantable housing, attention is directed to Lekholm who teaches that the heart sound detector can be located on a separate line or on an electrode lead. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the sensor as taught by Carlson et al. with the sensor of Lekholm, since applicant has not disclosed that this location of the sensor provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any location for the sensor such as the external location taught by Lekholm for detecting heart sounds.

9. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Sholder et al. (5,899,928). Although Carlson et al. discloses the claimed invention except for explicitly teaching the interface circuit is configured to communicate using radio frequency or optical signals, attention is directed to Sholder et al. who teaches it is well known to use RF and optical signals for communication between implantable devices and external devices. (Col. 8, lines 52-55). It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the interface circuit as taught by Carlson et

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al. with an interface circuit that communicates via RF or optical signals, since applicant has not disclosed that these particular communication means provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any means for communication such as the RF or optical signal communication taught by Sholder et al. for communication between an implantable device and an external device.

10. Claims 7, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. Although Carlson et al. discloses the claimed invention except for explicitly teaching the transmitted data includes raw data determined by digitizing the sensed signals, the Carlson device would be capable of doing so since it is capable of transmitting processed data. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to provide raw digitized data for transmittal to the external system rather than processed data as taught by Carlson et al., since applicant has not disclosed that doing so provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any data transmitted to the external system for measuring signals within the body.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Tockman et al. (5,540,727). Although Carlson et al. discloses the claimed invention except for explicitly teaching the second sensor is located in a left side of a heart, attention is directed to Tockman who shows a similar device with a sensor (27, 29) located in the left side of the heart for sensing ventricular electrical signals (Col. 3, lines 20-28). It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to locate the second sensor in a left side of a heart, since applicant has not disclosed that this

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particular location provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any location for the second sensor such as the location in a left heart taught by Tockman et al. for sensing left ventricular electrical signals.

12. Claims 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (6,409,675) in view of Bauman et al. (5,836,987). Although Turcott shows receiving ECG signals and generating control signals including using ECG data (Col. 15, lines 35-49), Turcott fails to show using a surface ECG. Bauman et al. shows a similar device for measuring heart sounds from an implantable system. Bauman et al. teaches that in conjunction with the implanted system either an internal or external (surface) electrogram can be used (Col. 2, lines 61-67). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ external (surface) ECG data for the ECG data of Turcott wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Turcott device.

Regarding claim 61, Turcott further shows outputting relative timing information between the heart sounds and ECG events on the output device (Col. 16, line 10- Col. 17-line 13).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Noren et al. (5,427,112), Nilsson (6,044,299), Salo et al. (5,334,222), Kadhiresan (5,935,081) each show implantable devices with heart sound sensors and the capability of measuring ECG's, as well as including telemetry.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185.

The examiner can normally be reached on M-F, 8:00 am - 4:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



kld

November 15, 2002



KENNEDY SCHAETZLE
PRIMARY EXAMINER
11-18-02